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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT

PAPER NUMBER

3737

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-11, 19-20, and 26 have been considered but they are not persuasive. In response to applicant's argument that the references fail to show a telemetrically coupled IMD and an MRI imaging device wherein their respective operating timing schemes are synchronized and, furthermore, that some of the timing schemes for the IMD are intended to trigger an arrhythmia. However, the examiner disagrees with applicant's assertions. In col. 11, lines 7-21, the Foster et al. reference specifically teaches of timing of the pacemaker device with the MRI device, see also figures 6b-d. Additionally, Foster et al. disclose that the IMD can include an implantable pacemaker connected to the heart for furnishing electrical impulses to the heart (see abstract, see claim 22). The implantable cardioverter/defibrillator pacemaker inherently includes application to trigger an arrhythmia (col. 12, lines 24-43; col. 11, lines 22-30). The MRI sends out signals that are detected by the IMD and the signals are evaluated to determine whether or not to disable portions of the IMD. Foster et al. disclose timing of the IMD with the MRI system (col. 10- lines 26-67). Based on the above observations, the Foster et al. reference teach or suggest a telemetrically coupled IMD and an MRI imaging device wherein their respective operating timing schemes are synchronized and intended to trigger an arrhythmia. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 19-20 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases “imaging the volume of tissue upon a display”, “myocardial tissue”, “beat-by-beat basis”, “a plurality of different timing information” and “discretely-timed” are considered to be new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1, 4-6, 8-10, 19-20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 6,925,328) in view of Paul et al. (5,697,958).**

Foster et al. discloses a magnetic resonance imaging (MRI) device comprising: a magnet to generate a magnetic field (col. 1, lines 24-41); an electromagnetic radiation source to apply MRI electromagnetic radiation bursts (col. 1, lines 24-41) to the patient;

an imaging unit to generate images of patient following application of radiation bursts (col. 8, lines 37-55); a receiver to receive information from an implantable medical device (IMD) (abstract); and a control unit to coordinate application of the electromagnetic radiation bursts based on the information (see Figure 5), the information defines a timing of stimulation pulses applied to a patient with the IMD, in which the received information defines a timing of the stimulation applied to the patient by the IMD (col. 7, lines 5- 67). Foster et al. disclose that the IMD can include an implantable pacemaker connected to the heart for furnishing electrical impulses to the heart (see abstract, see claim 22). The implantable cardioverter/defibrillator pacemaker inherently includes application to trigger an arrhythmia (col. 12, lines 24-43; col. 11, lines 22-30). The MRI sends out signals that are detected by the IMD and the signals are evaluated to determine whether or not to disable portions of the IMD. MRI inherently includes application of gradient magnetic fields. An operator who sets in the image sequence data into the MRI system controller or the microprocessor of the IMD can comprise the programmer which disables portions of the IMD. Foster et al. disclose timing of the IMD with the MRI system (col. 10- lines 26-67).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 2, 3, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 6,925,328) in view of Greatbatch (US 2003/0109901).**

Foster et al. teaches all the limitations of the claimed subject matter as applied in claim 1, except for mentioning specifically a pacemaker which collects information of a cardiac cycle, and the received information includes an indication of sensed cardiac activity and physiologic conditions measured by the IMD, an indication of one or more stimulations applied by the IMD.

However, a pacemaker which collects information of a cardiac cycle, and the received information includes an indication of sensed conditions measured by the IMD, an indication of one or more stimulations applied by the IMD is considered conventional in the art by the teachings of Greatbatch (see Abstract and Figure 1).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Foster et al., with the above discussed enhancements would have been considered obvious because such modifications would have provided a stand-alone cardiac stimulating and monitoring system during MRI scanning without operational disruption and without physiological injury to the patient's heart.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/  
Supervisory Patent Examiner, Art  
Unit 3737

JFR